

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

VIVIAN OH, Individually and on Behalf of  
All Others Similarly Situated,

Plaintiff,

v.

GENZYME CORPORATION and HENRI A.  
TERMEER,

Defendants.

No:

**CLASS ACTION COMPLAINT AND JURY TRIAL DEMAND**

Plaintiff Vivian Oh, by and through her attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, her counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Genzyme Corporation ("Genzyme" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Genzyme; and (c) review of other publicly available information concerning Genzyme. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

**NATURE OF THE ACTION**

1. This is a securities class action brought by Plaintiff Vivian Oh ("Plaintiff") on behalf of all purchasers (the "Class") of the common stock of Genzyme Corporation ("Genzyme" or the "Company") between June 26, 2008 and July 21, 2009, inclusive (the "Class

Period”) seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Defendant Genzyme is a leading biotechnology company based in Cambridge, Massachusetts. The Company manufactures and distributes therapeutic products for the treatment of a variety of disorders including, among other things, rare inherited disorders, kidney disease, orthopedics, transplant and immune disease.

3. Throughout the Class Period, Defendants failed to disclose serious problems and operational deficiencies at two of Genzyme’s manufacturing facilities, which caused a shortage of one of the Company’s top-selling products, Myozyme – a treatment for a rare genetic disorder – and delayed approval of a new version of Myozyme, a drug known as Lumizyme. The manufacturing problems also forced the Company to halt production of two other top-selling products, Cerezyme and Fabrazyme, resulting from contamination at one of the facilities.

4. In the fall of 2008, after two inspections of a Genzyme manufacturing facility in Allston, Massachusetts (the “Allston facility”), the federal Food and Drug Administration (“FDA”) noted practices at the facility that deviated from the FDA’s Good Manufacturing Process (“GMP”) standards. Genzyme failed to promptly disclose the FDA’s observations, even though Defendants knew that the FDA would not grant marketing approval for Lumizyme (the new version of Myozyme) until those problems were corrected.

5. Also in 2008, two instances of contamination at Genzyme manufacturing facilities, one in Geel, Belgium, and the other at the Allston facility, were not timely disclosed to investors even though the contamination negatively affected Genzyme’s ability to meet consumer demand for Myozyme and eventually caused a supply shortage of that product.

6. The deficient manufacturing practices at the Allston facility were not disclosed

until June 2009, until after the Company received a “Warning Letter” from the FDA on February 27, even though the contamination prevented Genzyme from manufacturing sufficient quantities of Myozyme to meet demand, and prevented the Company’s first quarter 2009 earnings from meeting analysts’ expectations

7. Then, on July 22, 2009, the day after the end of the Class Period, Genzyme slashed its earnings and revenue forecasts for 2009, including its revenue projections for its leading drugs, Myozyme, Cerezyme and Fabrazyme.

8. As a result of Defendants’ fraudulent misrepresentations about Genzyme’s operations and their failure to disclose materially adverse information affecting the Company’s business, operations and prospects, Genzyme’s stock has fallen approximately 35%, from a Class Period high of over \$83 per share, to the low-to-mid-\$50 range after disclosure of the problems.

9. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

### **JURISDICTION AND VENUE**

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act (15 U.S.C. §78aa).

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. §1391(b) and Section 27 of the Exchange Act (15 U.S.C. §78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts

charged herein, including the preparation and dissemination of materially false and/or misleading information, occurred in substantial part in this District.

13. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

### **THE PARTIES**

14. Plaintiff Vivian Oh purchased Genzyme common stock during the Class Period, as set forth in the attached Certification, and was damaged thereby.

15. Defendant Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal executive offices located at 500 Kendall Street, Cambridge, Massachusetts. At all relevant times, the Company's shares traded on the Nasdaq stock exchange under the symbol "GENZ."

16. Defendant Termeer was, at all relevant times, Chairman, President and Chief Executive Officer of Genzyme. By virtue of his high-level positions within the Company, Termeer directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company, its business, operations, finances, and financial condition. Termeer was involved in drafting, producing, reviewing, approving and/or disseminating the materially false and misleading statements and information alleged in this Complaint, knew or with extreme recklessness disregarded the fact that materially false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the securities laws.

### **CLASS ACTION ALLEGATIONS**

17. Plaintiff brings this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure, on behalf of Plaintiff and a Class consisting of all those who purchased the common stock of Genzyme between June 26, 2008 and July 21, 2009, inclusive, and who were damaged thereby. Excluded from the Class are Defendants and their legal representatives, heirs, successors and assigns; those who were officers, directors or insurers of Genzyme during the Class Period; members of Termeer's immediate family, and any entity in which any of the foregoing have or had a controlling interest.

18. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Genzyme's common stock was actively traded on the Nasdaq stock exchange. According to the Company's 2008 Form 10-K, there were more than 271 million shares of Genzyme common stock outstanding as of January 31, 2009. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Genzyme or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

19. Plaintiff's claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the federal securities laws.

20. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

21. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a. whether the federal securities laws were violated by Defendants' conduct as alleged in this Complaint;
- b. whether statements made by Defendants to the investing public during the Class Period misrepresented and/or omitted material facts about the business, operations and profitability of Genzyme;
- c. whether Defendants acted with scienter; and
- d. to what extent the members of the Class have sustained damages and the proper measure of damages.

22. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, as joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impracticable for members of the Class to individually redress the wrongs done to them. Plaintiff anticipates no difficulty in the management of this action as a class action.

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

23. Genzyme, is a leading international biotech company. Genzyme's therapeutic products are sold to patients in approximately 100 countries, and are focused on treating rare inherited disorders, kidney disease, orthopedics, transplant and immune disease, and diagnostic testing. For purposes of financial reporting, the Company is organized into four segments:

(1) Genetic Diseases, (2) Cardiometabolic and Renal, (3) Biosurgery and (4) Hematologic Oncology.

24. Many of Genzyme's products are "biologics" – *i.e.*, derived from natural sources (human, animal, or microorganism) – rather than the traditional, chemically synthesized pharmaceutical compounds. Because biologics tend to be heat-sensitive and susceptible to contamination, biologics manufacturing requires adherence to aseptic procedures throughout the manufacturing process.

25. Three of the Genzyme's biologics products – Cerezyme, Fabrazyme, and Myozyme – are manufactured by the Genetic Diseases segment at the Company's facility in Allston, Massachusetts.

26. Cerezyme is Genzyme's top revenue-producing product. Cerezyme is an enzyme replacement therapy for the treatment of Gaucher disease, which is caused by a hereditary enzyme deficiency which can lead to an accumulation of fatty deposits in the spleen, liver, kidneys, lungs, brain and bone marrow, and can cause liver malfunction, severe neurologic complications and anemia.

27. Fabrazyme is Genzyme's third-highest revenue generator. Fabrazyme, a recombinant form of the human enzyme alpha-galactosidase, is a treatment for Fabry disease, which is caused by a deficiency of enzymes needed to metabolize lipids and other fat-like substances. If untreated, these substances can accumulate to harmful levels in the eyes, kidneys, autonomic nervous system and cardiovascular system.

28. A third biologic, Myozyme, is the only available treatment for Pompe disease, a rare genetic disorder which causes glycogen to accumulate in certain tissues and can lead to heart problems, breathing difficulties and muscle weakness. When Pompe disease occurs early in life,

it can progress quickly and is usually fatal without treatment. Thus, treatment is a high priority for infants and children who have been diagnosed with the disease.

29. Genzyme initially manufactured Myozyme at the 160 liter (“L”) bioreactor scale, and then scaled up the process to produce larger quantities, in larger bioreactors, moving next to the 2000L scale. In April 2006, Genzyme received FDA approval to sell Myozyme produced at the 160L scale in the United States, and also began selling Myozyme produced at the 2000L scale overseas. Soon thereafter, Genzyme sought approval to sell the version produced at the 2000L scale in the United States, but in April 2008 the FDA indicated that Genzyme would be required to submit a separate biologics license application (“BLA”) to gain approval for Myozyme produced at the 2000L scale. In the FDA’s view, the two versions should be classified as different products because of differences in the carbohydrate structures of the molecules. In response to the FDA’s decision, Genzyme submitted a separate BLA for the 2000L scale version on May 30, 2008, and indicated that this version would be marketed under the name “Lumizyme.”

**Defendants’ Materially False and Misleading Statements During the Class Period**

30. On June 26, 2008, the first day of the Class Period, during a presentation at the Jefferies Healthcare Conference which was attended by securities analysts covering the Company, a Genzyme executive touted significant sales growth for Cerezyme, Fabrazyme and Myozyme. However, as Defendants knew or recklessly disregarded and failed to disclose, the Company at that time faced material risks to the future of its business because Genzyme’s



manufacturing processes for those products were not in compliance with FDA regulations related to good manufacturing practices (“GMPs”).<sup>1</sup>

31. On July 23, 2008, Genzyme issued a press release announcing its financial results for second quarter 2008. The press release, titled “Genzyme Reports Strong Second-Quarter Growth; Delivers Solid Financial Performance While Building for the Future,” stated the following, in pertinent part:

CAMBRIDGE, MA—Genzyme Corporation (NASDAQ: GENZ) today reported strong sales and profit growth in the second quarter, along with significant progress in its commercial and clinical programs.

Revenue increased 25 percent to approximately \$1.171 billion from \$933.4 million in last year’s second quarter. The increase was driven by growth across all areas of the business.

GAAP net income was \$69.6 million, or \$0.25 per diluted share, compared with \$83.8 million, or \$0.31 per diluted share, in the second quarter a year ago. GAAP net income reflects the fee for the license to mipomersen, a highly promising cholesterol-lowering drug in late-stage development.

Non-GAAP net income increased to \$268.5 million from \$238.7 million in last year’s second quarter. Non-GAAP earnings increased to \$0.98 per diluted share from \$0.88.

Genzyme continues to reinvest cash from operations to build a foundation for long-term growth. In the second quarter, the company generated approximately \$329 million in cash from net income prior to one-time events and proceeds from the issuance of common stock. The company made a \$175 million payment to Isis Pharmaceuticals to secure the rights to mipomersen, significantly strengthening its late-stage pipeline. Genzyme also invested approximately \$130 million in capital projects, predominantly focused on expanding manufacturing capacity to meet current and anticipated product demand. To reduce the dilutive effect of equity compensation, the company used a portion of its cash to repurchase 1 million shares under its three-year stock buyback program.

“It was a strong and highly productive quarter,” said Henri A. Termeer, Genzyme’s chairman and chief executive officer. “We delivered solid financial results, set in place a number of catalysts that will drive near-term growth, and continued to build the company to grow beyond 2011.”

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<sup>1</sup>GMPs are the quality systems which manufacturers of FDA-regulated products (such as biologics) must establish and follow to help ensure that their products consistently meet applicable requirements and specifications and are safe and effective for their intended use.

Over the next 12 months, Genzyme anticipates six potential approvals for new products or broader indications for existing products. These catalysts will provide significant near term momentum:

Genzyme expects FDA approval by the end of this year for alglucosidase alfa (Myozyme®) produced at the 2000L bioreactor scale, following the submission of a BLA on May 30. European approval of Myozyme produced at the 4000L scale is expected in the first half of next year.

\* \* \*

Genzyme continues to expect non-GAAP earnings for this year of approximately \$3.90 per diluted share. GAAP earnings in 2008 are expected to be approximately \$2.20 per diluted share. The GAAP estimate now reflects Genzyme's equity investment in Isis Pharmaceuticals, the mipomersen licensing fee, along with anticipated amortization, stock-compensation expenses and the effect of contingent convertible debt.

#### Second-Quarter Product Sales

Within the Therapeutics business, Myozyme revenue rose 65 percent compared with last year's second quarter, despite the constraint on U.S. sales resulting from the delay in approval of 2000L-scale production. Revenue increased to \$77.2 million from \$46.7 million in the same period a year ago. The FDA is expected to convene an advisory committee meeting in October to discuss the BLA for alglucosidase alfa produced at the 2000L-scale, as required for all new drug and biologics license applications under the FDA Amendments Act enacted last year. FDA approval of 2000L-scale production is needed to provide broader access to product for adult patients in the United States.

The launch of Myozyme has been more rapid than the launch of any of Genzyme's other treatments for lysosomal storage disorders, driven by faster than expected adoption by physicians and patients and consistent support from health authorities in more than 40 countries. To meet the global demand for Myozyme, Genzyme is working to secure approval of production at its 4000L bioreactor scale manufacturing plant in Belgium, which would significantly expand capacity. The company is conducting process validation runs for Myozyme produced at the 4000L-scale, which it expects to complete this year and subsequently file for EMEA approval. The company expects that European authorities will approve Myozyme production at the facility during the first half of 2009. Approval of 4000L-scale production in Belgium will be necessary to meet the anticipated global demand for Myozyme. Product supply in 2009 is expected to be particularly tight until the Belgium plant is approved.

Genzyme's other treatments for lysosomal storage disorders also continue to experience strong, double-digit growth. Second-quarter Cerezyme® (imiglucerase for injection) sales rose 13 percent to \$319.4 million, compared with \$283.0 million in the previous second quarter. Sales of Fabrazyme® (agalsidase beta) grew 21 percent, rising to \$126.6 million from \$104.3 million. Sales of Aldurazyme® (laronidase) increased 33 percent to \$38.8 million, compared with \$29.1 million in the second quarter last year when the product's sales were recorded under the joint venture with BioMarin Pharmaceutical Inc.

The company also reported preliminary results from a Phase 2 trial of its investigational oral therapy for Gaucher disease Genz-112638. The results were consistent with those observed for patients beginning enzyme replacement therapy, and they highlight the potential of this compound to provide a convenient treatment alternative for patients and a broader range of treatment options for physicians. Genzyme is developing protocols for two Phase 3 trials that it expects to initiate early next year.

\* \* \*

32. Defendants knew or recklessly disregarded that the July 23, 2008 press release was materially false and misleading because it failed to disclose the Company's ongoing non-compliance with GMPs.

33. On October 22, 2008, Genzyme issued a press release announcing the Company's financial results for third quarter 2008. The press release was titled "Genzyme Reports Strong Third-Quarter Sales and Earnings Growth; Company Expects 2009 Non-GAAP EPS of Approximately \$4.70," and stated, in pertinent part, the following:

Genzyme Corporation (NASDAQ: GENZ) announced today that third-quarter revenue rose 21 percent to \$1.160 billion, compared with revenue of \$960.2 million in the same period a year ago. The increase was driven by double-digit growth in every Genzyme business unit.

GAAP net income was \$119.6 million, or \$0.42 per diluted share, compared with \$159.3 million, or \$0.58 per diluted share, in last year's third quarter. Net income in this year's third quarter reflects a \$100 million licensing fee for rights to PTC124, a promising genetic disease drug in late-stage development.

Non-GAAP net income rose 20 percent to \$289.8 million from \$241.3 million in the third quarter last year. Non-GAAP earnings grew 16 percent to \$1.04 per diluted share compared with \$0.90 per diluted share.

During the third quarter, Genzyme generated approximately \$481 million in cash from net income prior to one-time events and proceeds from the issuance of common stock. The company has increased its cash position to approximately \$1.5 billion while making investments to support long-term growth, including investments to expand manufacturing capacity, to offset dilution by repurchasing shares, and to complete strategic transactions that strengthen its late-stage pipeline.

"The third quarter was a very strong quarter financially and also extremely productive in terms of building for the future," said Henri A. Termeer, chairman and chief executive officer of Genzyme Corp. "Our broad geographic diversification, solid cash position, and group of market-

leading products will allow us to sustain our growth through the current financial environment and over the longer term.”

Genzyme is on track to meet its goal of 20 percent compound average non-GAAP earnings growth from 2006 through 2011. For 2009, the company expects non-GAAP earnings to increase to approximately \$4.70 per diluted share. Non-GAAP earnings are projected to rise to approximately \$7.00 per diluted share by 2011.

These estimates include the impact of Genzyme’s redemption of its convertible senior notes. The company plans to redeem all \$690 million of these notes as of December 1, 2008. The notes are redeemable in cash or can be converted to common stock at the option of the noteholders at a conversion price of \$71.24 per share.

#### Near-Term Catalysts

Genzyme anticipates a number of potential approvals for new products or broader indications for existing products over the next several quarters. These catalysts will provide significant near term momentum:

FDA action on the BLA for Myozyme® (alglucosidase alfa) produced at the 2000L bioreactor scale is expected by November 29, 2008. An FDA advisory committee yesterday affirmed that the Late Onset Treatment Study established the clinical effectiveness of alglucosidase alfa produced at this scale.

European approval for 4000L-scale production of Myozyme is expected in the first half of next year.

\* \* \*

Genzyme also anticipates achieving a number of important milestones within its late-stage pipeline that will have a significant near-term business impact. These include the initiation or completion of pivotal clinical studies and the publication of key study results. These milestones are detailed after the following summary of third-quarter sales.

#### Third-Quarter Product Sales

Within the Therapeutics business, Myozyme revenue increased to \$76.7 million, 43 percent greater than revenue of \$53.6 million in the same period last year. U.S. Myozyme sales have been constrained by the delay in approval for 2000L-scale production. Yesterday, the Endocrinologic and Metabolic Drugs Advisory Committee affirmed by a vote of 16-1 that the LOTS study established the clinical effectiveness of alglucosidase alfa produced at the 2000L scale. Genzyme expects FDA action on its BLA for this product by the PDUFA date of November 29. Approval of 2000L-scale production is needed to provide broader access to treatment for patients with late-onset Pompe disease in the United States.

Genzyme is also preparing to seek clearance from European authorities for 4000L-scale production of Myozyme at its manufacturing facility in Belgium. The company has successfully

completed the required three consecutive process validation runs. In addition, preliminary data on the comparability of 4000L product with 2000L product are encouraging. Genzyme anticipates submitting an application for 4000L production in early January, and EMEA approval is anticipated during the first half of next year. Approval of 4000L-scale production will be necessary to meet the anticipated global demand for Myozyme. Product supply is expected to remain tight until the 4000-L process is approved.

Third-quarter sales of Fabrazyme® (agalsidase beta) increased 20 percent to \$125.6 million from \$104.6 million, driven primarily by an increase in the number of patients beginning therapy. Enrollment has begun in the post-marketing FIELD study of Fabrazyme, which is exploring additional dosing options that may facilitate early treatment of Fabry disease. Third-quarter sales of Cerezyme® (imiglucerase for injection) rose 8 percent to \$309.3 million, compared with \$286.1 million in last year's third quarter. Sales of Aldurazyme® (laronidase) were \$38.2 million, 18 percent higher than sales of \$32.3 million in the same period a year ago. Aldurazyme sales in last year's third quarter were recorded as joint venture revenue.

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Third-quarter revenue for the Genetics business increased 12 percent to \$82.1 million, compared with \$73.1 million in last year's third quarter. This growth was driven in part by the continuing demand for prenatal screening for genetic conditions. Additionally, Genzyme is experiencing increasing demand for its diagnostics tests that assist oncologists in selecting the appropriate treatment for patients with certain types of cancer. The increasing recognition of the value of diagnostics in personalized medicine will continue to fuel organic growth in the Genetics business.

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34. Defendants knew or recklessly disregarded that the October 22, 2008, press release was materially false and misleading because it failed to disclose the Company's GMP violations, despite that from September 15 through October 10, 2008, FDA officials had conducted a GMP inspection at the Allston facility and noted significant deviations from GMP compliance, including observations relating to Genzyme's procedures designed to prevent microbiological contamination of sterile drug products, controls for in-process monitoring during bulk drug substance manufacturing, and maintenance of equipment. These "Inspectional Observations" (formally, a Form FDA 483) were sent to Termeer on or about October 10, 2008.

35. On October 31, 2008 Genzyme responded to the FDA with a plan to address the

Inspectional Observations, with the aim of resolving all the issues by March 31, 2009. None of this activity was disclosed to the public, even though a failure to cure the violations could impact Genzyme's ability to continue its operations at the Allston facility, which in turn would impact Genzyme's revenue and profitability.

36. The October 22, 2008 press release also failed to disclose that in September 2008 Genzyme had discovered a problem at its plant in Geel, Belgium, when, for unknown reasons, cell productivity declined, which impacted its ability to manufacture Myozyme on time. This contributed to Genzyme's "tight" supply of Myozyme, but was not disclosed in the Company's press releases or SEC filings during 2008. Instead, Genzyme misleadingly implied that the shortage was the result of a growth in demand that had outpaced the growth in supply – not the result of manufacturing problems.

37. On January 13, 2009, the Company issued a press release announcing Genzyme's financial results for fourth quarter 2008. The press release was titled "Genzyme Reports Strong Fourth-Quarter and 2008 Revenue Growth; Provides Outlook for Sustainable Growth Through 2011 and Beyond," and stated the following, in pertinent part:

Genzyme Corp. (NASDAQ: GENZ) announced today that revenue rose 13 percent in the fourth quarter of 2008 and 21 percent for the year.

Fourth quarter estimated revenues were \$1.17 billion, reflecting an approximate negative \$39 million impact of foreign exchange, compared with \$1.04 billion in the same period in 2007. For the year, revenue grew to \$4.6 billion from \$3.8 billion in 2007. Genzyme expects fourth quarter non-GAAP earnings per diluted share of between \$1.01 and \$1.04.

Genzyme reported these and other preliminary, unaudited figures in conjunction with a presentation by Chairman and Chief Executive Officer Henri A. Termeer at the JPMorgan 27th Annual Healthcare Conference in San Francisco. The company will report full financial results for 2008 on February 11.

"We made great progress during 2008 in a number of areas," said Mr. Termeer. "We delivered strong financial results, continued to grow our existing products, secured new product approvals, advanced pivotal clinical trials, and significantly strengthened our late-stage pipeline."

Mr. Termeer today detailed Genzyme's outlook for continued strong growth in 2009 and the catalysts that will drive near and long-term momentum. This year, the company expects to:

Obtain regulatory approvals for larger-scale production of Myozyme® (alglucosidase alfa), which will help enable Genzyme to meet the rapidly increasing demand for the treatment, and provide capacity for the realization of the product's significant long-term potential.

Launch Mozobil® (plerixafor injection) in the United States and Europe, and Clolar® (clofarabine) for adult acute myelogenous leukemia in the United States, substantially expanding the company's hematologic oncology presence.

Launch Synvisc-One™ in the United States, the largest potential market for the product.

Obtain U.S. approval of a label expansion for Renvela® (sevelamer carbonate) to include the treatment of patients with chronic kidney disease who are not on dialysis, as well as E.U. approval of the treatment, significantly increasing the product's market size and long-term growth potential.

Move key late-stage products forward by completing a pivotal study of mipomersen in homozygous familial hypercholesterolemia; advancing pivotal studies of alemtuzumab for MS; initiating pivotal studies of an oral therapy for Gaucher disease; and advancing late-stage studies of Prochymal for graft vs. host disease and PTC124 for Duchenne muscular dystrophy.

#### Delivering Sustainable Growth

Genzyme is on track to meet its goal of 20 percent compound average non-GAAP earnings growth from 2006 through 2011. For 2009, the company expects non-GAAP earnings to increase to approximately \$4.70 per diluted share. Revenues for 2009 are expected to be between \$5.2 and \$5.4 billion. Non-GAAP earnings are projected to rise to approximately \$7.00 per diluted share by 2011, and revenue that year is expected to reach \$7 billion. Genzyme expects a total of 16 new regulatory approvals from 2009 through 2012, which will contribute to the company's growth beyond 2011.

Genzyme currently has 12 number one products and has built its leadership role by pioneering a patient-focused, personalized medicine approach. This begins with clearly identified patient populations that have serious unmet medical needs, combined with the development of effective therapeutics, resulting in high-value products that become the standard of care.

The company has built a broad global infrastructure, with its products available in approximately 100 countries, 17 manufacturing sites in 9 countries, and more than 50 percent of its revenues coming from outside the United States. The geographic diversification of Genzyme's commercial and manufacturing operations provides competitive advantages and enables the company to manage the impact of exchange rate fluctuations. Genzyme has no debt and generates more than \$1 billion in cash annually. The company utilizes this cash flow to make

substantial investments in its global infrastructure, to repurchase shares and to complete strategic transactions.

## 2008 Performance & Long-Term Business Outlook

The Genetic Disease segment has formed the core of Genzyme's business to date, and the growth potential for this segment remains strong. Genzyme expects sales of enzyme replacement therapy products to grow at a compound average of approximately 15 percent over the five-year period from 2006-2011. At the same time, the emerging franchises of Genzyme's portfolio are expected to make an increasingly greater contribution to the company's growth, underscoring the beneficial impact of diversification. Revenue from these emerging franchises is expected to grow at a compound average of approximately 19 percent from 2006-2011.

### Genetic Diseases

Genzyme's Genetic Disease segment grew 26 percent in 2008 to \$2.2 billion from \$1.8 billion in 2007. Over the longer term, peak revenues for this segment are expected to approximately double to \$4 billion. Genzyme continues to expand upon its leadership position in the treatment of lysosomal storage disorders. Within this field, the company has successfully introduced four enzyme replacement therapies globally. The recent launch of Myozyme has been the strongest product launch in the company's history. Myozyme fourth-quarter revenue increased to \$75 million, 20 percent greater than revenue of \$62 million in the same period last year. During the fourth quarter revenue was impacted because Genzyme did not promote the product in the United States due to the delay in approval for 2000 L bioreactor scale production. Myozyme sales in 2008 reached \$296 million compared with sales of \$201 million in 2007.

Genzyme currently has U.S. approval to sell Myozyme produced at the 160 L scale; approval of 2000 L scale production is needed to provide broader access to treatment for U.S. patients with late-onset Pompe disease. In October, an FDA advisory committee affirmed by a vote of 16-1 that the clinical effectiveness of Myozyme produced at this scale had been established, and Genzyme expects FDA action on its BLA by February 28. The product will be called Lumizyme™ (αglucosidase alfa).

On December 22, Genzyme submitted an application to the European Medicines Evaluation Agency seeking approval to produce Myozyme at the 4000 L scale at its manufacturing facility in Geel, Belgium. The 4000 L manufacturing process is expected to provide adequate supply to meet the strong global demand for Myozyme for the foreseeable future. Under the standard review process, action by the European Commission would be expected in April. Genzyme has requested expedited review of its application. The company anticipates filing for U.S. approval for the 4000 L manufacturing process during the first half of this year. From January through April of this year, inventory levels are expected to be so tight that there is a risk of delays in order fulfillment and consequent potential interruptions in therapy. Genzyme participated in a series of meetings with a group of stakeholders from the Pompe medical community to develop guidance to optimally manage the existing product supply until the 4000 L manufacturing process is approved in Europe. All stakeholders are working toward a goal of safeguarding Myozyme supply for infants and children.



Fourth-quarter sales of Fabrazyme® (agalsidase beta) were \$126 million, up 10 percent from \$115 million in the same quarter a year ago. For the year, sales grew 17 percent to \$494 million, compared with \$424 million in the previous year. Genzyme recently began enrollment in the post-marketing FIELD study of Fabrazyme, which is exploring additional dosing options that may facilitate earlier treatment of Fabry disease.

Fourth-quarter sales of Cerezyme® (imiglucerase for injection) were \$305 million, compared with sales of \$300 million in the fourth quarter a year ago. For the year, sales were \$1.2 billion, compared with \$1.1 billion the year before. During the first half of 2009, the company expects to begin two phase 3 studies of the small molecule Genz-112638 for Gaucher disease. Final results from the open-label phase 2 study of the compound are expected to be available early this year. Preliminary results from an interim analysis were consistent with those observed for patients beginning enzyme replacement therapy, and they highlight the potential of this compound.

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38. Defendants knew or recklessly disregarded that the January 13, 2009, press release was materially false and misleading because it failed to disclose (i) Genzyme's noncompliance with GMP at its Allston facility; (ii) contamination problems at the Geel, Belgium, facility; (iii) that in November 2008, Genzyme had experienced the same slowdown in cell growth at the Allston facility that it had experienced in the Geel facility a few months earlier, and consequently was unable to produce the expected quantities of Myozyme, creating the possibility of an upcoming shortage; and (iv) that the problems at the Geel and Allston facilities were the actual cause of the supply constraints creating "a risk of delays in order fulfillment and consequent interruptions in therapy."

39. Also in January 2009, the problems at Genzyme's manufacturing facilities began to filter into press reports. On January 20, 2009, *TheStreet.com*, in an article titled "Genzyme Drug Rationing Urged Amid Shortage" by Adam Feuerstein, reported the following:

European regulators have recommended rationing of a Genzyme ... drug to treat a rare genetic disorder due to unspecified manufacturing problems.

The ... EMEA said Friday that infants, children and adolescents with Pompe

disease should be given priority access to Genzyme's Myozyme due to a supply shortage that is expected to last several months.

The EMEA said the Myozyme shortage was caused by an increase in demand for the drug as well as unspecified manufacturing problems at some sites where Genzyme makes the drug.

Deutsche Bank biotech analyst Mark Schoenebaum said the new Myozyme manufacturing issues disclosed by the EMEA Friday could reduce Myozyme to equal or below fourth-quarter 2008 levels.

"The EPE impact should be modest given Genzyme's ability to manage expenses," he added. Schoenebaum ha[d] a hold rating on Genzyme.

(emphasis added).

40. On February 11, 2009, Genzyme issued a press release announcing its fourth-quarter and full-year 2008 financial results. The press release, titled "Strong Fourth Quarter for Genzyme Concludes Productive Year; Non-GAAP EPS Reaches \$1.04 in Fourth Quarter and \$4.00 for 2008; Company Provides Confident Outlook for 2009," and stated the following, in pertinent part:

Genzyme Corp. (NASDAQ: GENZ) today announced solid fourth-quarter revenue and earnings growth and provided guidance for 2009 that underscored its positive outlook for the year.

GAAP net income rose to \$86.7 million, or \$0.31 per diluted share, compared with \$78.9 million, or \$0.29 per diluted share, in the prior fourth quarter. Non-GAAP net income increased 16 percent to \$288.5 million compared with \$249.2 million in the fourth quarter of 2007. Non-GAAP earnings rose 14 percent to \$1.04 per diluted share from \$0.91 per diluted share in the same period in 2007.

GAAP figures for the quarter include a non refundable upfront fee to Osiris Therapeutics Inc. for a late-stage product candidate, amortization and stock compensation expenses, and a charge to write off overhead and material associated with incomplete process validation runs at the company's Belgium manufacturing facility.

"We had an excellent year last year and exceeded our earnings expectations despite the economic environment and the challenges we faced with Myozyme," said Henri A. Termeer, Genzyme chairman and chief executive officer. "We delivered on our financial objectives but did not ignore our future. We continued to expand and invest in our pipeline and now have seven exciting late-stage programs with the potential to sustain our growth over the long term. Genzyme is stronger today than it was a year ago, and we feel confident about our future."

As previously announced, fourth-quarter revenue rose 13 percent to \$1.17 billion, reflecting an approximate \$39 million negative impact of foreign exchange, compared with \$1.04 billion in the same period in 2007.

Individual product sales for the fourth quarter and the year, along with expectations for the longer-term growth of Genzyme's business segments, were detailed in a January 13, 2009, press release coinciding with the company's presentation at the JPMorgan Healthcare Conference.

## 2008 Results

Total revenue in 2008 increased 21 percent to \$4.6 billion from \$3.8 billion in 2007. GAAP net income was \$421.1 million, or \$1.50 per diluted share, compared with \$480.2 million, or \$1.74 per diluted share, in 2007. Non-GAAP net income increased 18 percent to \$1.1 billion, compared with \$939.9 million in 2007. Non-GAAP earnings increased 15 percent to \$4.00 per diluted share from \$3.47 in 2007.

Genzyme generated approximately \$1.5 billion in cash predominantly from operations in 2008 and utilized this cash flow to substantially eliminate all debt, invest in its global infrastructure, repurchase shares, and complete strategic transactions that significantly strengthened its late-stage pipeline.

## Financial Guidance for 2009

### Earnings

Genzyme is on-track to achieve its goal of 20 percent compound average non-GAAP earnings growth from 2006 – 2011. Non-GAAP earnings are projected to rise to approximately \$7.00 per diluted share by 2011.

Non-GAAP earnings in 2009 are expected to increase to \$4.70 per diluted share. GAAP earnings, which include amortization and stock compensation expenses, are expected to reach \$3.50 per diluted share.

Non-GAAP earnings in the first quarter of 2009 are expected to be similar to earnings for the fourth quarter of 2008. Genzyme anticipates that its non-GAAP earnings will accelerate starting in the second quarter, as two key regulatory approvals for Myozyme® (alglucosidase alfa) are secured: E.U. approval of Myozyme produced at the 4000 L scale, which will help provide the capacity to meet the strong global demand for the product; and U.S. approval of Myozyme produced at the 2000 L scale, which will be called Lumizyme™ (alglucosidase alfa), giving the company the ability to promote the Pompe disease therapy produced at this scale in the U.S. market. Mozobil™ (plerixafor injection), which was launched last month, will also help drive earnings growth.

### Revenue

Revenue is expected to reach \$5.2 – \$5.4 billion in 2009. This reflects an approximate \$150 million unfavorable impact of foreign exchange. Genzyme anticipates strong volume growth in all five of its business segments:

Total revenue for the Genetic Disease segment is expected to reach \$2.47 – \$2.53 billion this year, compared with \$2.23 billion in 2008.

Within this segment, Myozyme revenue is expected to increase to \$430 – \$440 million, compared with \$296 million in 2008. The company anticipates FDA action by February 28 on its filing for U.S. approval of Lumizyme. European Commission approval of Myozyme produced at the 4000 L scale would be expected in April under the standard review procedure. Genzyme has requested expedited review of its application.

Revenue for Fabrazyme® (agalsidase beta), an important growth driver that is performing well in a competitive marketplace, is expected to rise to \$560 – \$570 million in 2009 from \$494 million last year.

Cerezyme® (imiglucerase for injection) revenue is expected to reach \$1.25 - \$1.28 billion, compared with \$1.24 billion in 2008, reflecting its mature status and the impact of foreign exchange.

\* \* \*

#### Gross Margin

The non-GAAP gross margin for 2009 is expected to be approximately 75 percent of revenues, compared with 76 percent in 2008. The gross margin reflects underutilized capacity at the two plants where larger scale production of Myozyme is starting to come online. It also reflects changes in product mix.

#### Expenses

Non-GAAP selling, general and administrative expenses are expected to represent approximately 26 percent of revenue in 2009, lower than SG&A expenses of 27 percent of revenue in 2008. SG&A spending this year will reflect several major product launches, including Mozobil in the United States and Europe and Synvisc-One™, Lumizyme, and Clolar® (clofarabine) for adult AML in the United States.

Non-GAAP research and development spending is expected to represent approximately 16 percent of revenue in 2009, consistent as a percentage of revenue with R&D spending in 2008. Genzyme continues to make a significant investment in its pipeline to sustain its future growth. The company is currently conducting approximately 100 clinical trials.

\* \* \*

41. On Friday, February 27, 2009, Genzyme received two letters from the FDA. One

letter, which was addressed to Termeer and titled “Warning letter,” conveyed the FDA’s ongoing concerns regarding GMP compliance at the Allston facility. The other letter indicated that the FDA would withhold Lumizyme approval beyond the February 28 deadline until the problems at the Allston facility were resolved. By the end of the day, Genzyme had not disclosed either letter.

42. By the close of trading on the following Monday, March 2, 2009, the Company still had not disclosed the contents or existence of the FDA’s letters. However, after the market close, Genzyme issued a press release about the letters and announced a conference call to be held at 5:00 p.m. A few minutes before 5:00 p.m., Genzyme filed its Form 10-K with the SEC, which stated in pertinent part:

In September and October 2008, FDA officials conducted a Good Manufacturing Practices, or GMP, inspection of licensed therapeutic drug products, bulk drug substances and drug components manufactured at our Allston, Massachusetts facility. We manufacture Cerezyme, Fabrazyme and Myozyme and perform fill/finish for Aldurazyme and Thyrogen at this facility. After this inspection, the FDA officials issued a list of inspection observations known as a Form FDA 483. The form detailed inspectional observations considered by the FDA to be significant deviations from GMP compliance, including observations relating to our procedures designed to prevent microbiological contamination of sterile drug products; controls for in-process monitoring during bulk drug substance manufacturing, including our controls for bioburden monitoring; and maintenance of equipment and computer systems validation. We responded to the Form FDA 483 on October 31, 2008 with a plan and timeline to address the inspectional observations and provided a progress update on February 23, 2009 to the FDA. On February 27, 2009, we received a warning letter from the FDA that requested supplemental information in order to fully evaluate the adequacy of our corrective actions with respect to nine of the FDA’s sixteen observations in the Form FDA 483. We currently are reviewing the warning letter and plan to respond to the FDA in writing within fifteen business days of receipt of the letter as is required. We are committed to working cooperatively with the FDA regarding this matter. The issuance of the warning letter does not affect the continued distribution of our Genetic Diseases products currently on the market or our inventory currently on hand. We believe that the products produced at our Allston facility continue to meet the highest quality and safety standards.

Failure to correct the deviations cited in the FDA’s warning letter could result in

further regulatory action, including suspension of our license to manufacture products at the facility, or lead to a delay in the approval of new products. The FDA will not approve our application to market alglucosidase alfa produced at the 2000L scale [*i.e.*, Lumizyme] at our Allston facility until the issues identified in the warning letter are resolved to the FDA's satisfaction.

43. Thus Genzyme finally revealed for the first time that the FDA had found significant problems at the Allston facility, that these issues were the subject of ongoing discussions with the FDA, and that these issues created another obstacle delaying approval of Lumizyme.

44. However, Genzyme's March 2, 2009, disclosures were materially incomplete. Neither the press release nor the 10-K mentioned the contamination that had occurred at Genzyme's Geel and Allston facilities in the fall of 2008, which had disrupted the supply of Myozyme, impacting revenue for first quarter 2009.

45. In light of the developments with the FDA, and assuming a six-month delay in obtaining FDA approval for Lumizyme, Genzyme stated in its March 2 press release that its revised projections for Myozyme revenue in 2009 were in the range of \$370-\$380 million, down from the projections of \$430-\$440 million announced only a few weeks earlier.

46. On this news, Genzyme shares dropped in after-market trading over 6%, from its closing price of \$56.52 down to \$53.00 on March 2, 2009.

47. On March 3, 2009, with a full day of trading to absorb the belatedly disclosed negative news, Genzyme's shares closed at \$52.48, a total drop of \$4.04 per share (more than 7%) from their March 2 close, on trading volume twice that of March 2.

48. Also on March 3, 2009, an article by Matthew Herper titled "Genzyme Held Bad News as Shares Dropped," which was published in *Forbes.com*, noted that Genzyme had failed to disclose this material information to investors for three days:

Genzyme waited three days, including one trading day in which its stock dropped, before disclosing to investors that the [FDA] is delaying a key product.

The Cambridge, Mass.-based biotechnology firm said on a conference call Monday that it had received two letters from the FDA on Friday afternoon. ... But Genzyme did not disclose the existence of the two letters until late Monday, after trading on the Nasdaq had stopped. ....

When Genzyme did disclose the news, it said the delay would lower its 2009 profit by about 12 cents per share. Shares dropped another 5% [sic] in aftermarket trading.

“One would definitely have thought” the company had a duty to disclose the news earlier, says Geoffrey Porges, a biotechnology analyst at Sanford C. Bernstein. “People do read press releases over the weekend as well,” Porges says.

“We needed the opportunity to talk through the feedback with the FDA, and put together our communication,” says Lori Gorski, a Genzyme spokeswoman.

Gorski declined to say whether the communication with the FDA came before or after the market closed on Friday.

49. On March 11, 2009, an article by David Armstrong published in *The Wall Street Journal* and titled “FDA Warns Genzyme on Plant Conditions,” included excerpts of a redacted copy of the FDA’s February 27, 2009 warning letter, which it had obtained from the FDA. The article stated, in pertinent part:

[FDA] investigators found “significant objectionable conditions” during an inspection of” [the Boston plant].

The Feb. 27 letter outlines a number of deficiencies in the manufacturing process at the Boston plant. ...

FDA investigators inspected the plant from Sept. 15, [2008] through Oct. 10, [2008] and “documented significant deviations from current good manufacturing practice.”

\* \* \*

Much of the six-page letter involves technical critiques of the manufacturing process.

“The deficiencies described in this letter are indicative of your quality control unit’s failure to fulfill its responsibility to assure the identity, strength, quality and purity of your drug products and drug substances,” the letter says.

For instance, the FDA said Genzyme failed to perform maintenance on large aluminum freezers used to transport cell banks and was using freezers – called cryoshippers – beyond their stated life expectancy. [Genzyme Vice President Mark] Bamforth says the company has changed its procedures following the inspection.

50. The article further states that Bamforth “said the company has addressed 80% of the problems cited by the FDA and expects to resolve all of the issues by the end of April. ... He said the Boston plant continues to produce treatments and that ‘the efficacy and safety of our products is unchanged. ‘”

51. As a result of this news, on March 11, 2009, Genzyme’s stock price dropped \$2.37 per share, or 4.3%, to close at \$52.82. However, the contamination problems at the Geel and Allston facilities remained undisclosed to investors.

52. On April 22, 2009, Genzyme issued a press release announcing the Company’s first quarter 2009 financial results. The press release, titled “Genzyme Reports Solid Financial Results for the First Quarter of 2009; Reiterates Outlook for the Year,” reported growth in first quarter earnings, but profit and revenue below Wall Street expectations. The press release stated the following, in pertinent part:

Genzyme Corp. (NASDAQ: GENZ) today reported that first-quarter revenue rose to \$1.15 billion, compared with \$1.10 billion in the same period a year ago, an increase of 4 percent. Including the \$66 million impact of unfavorable currency exchange rates, revenue grew 10 percent in the first quarter.

GAAP net income rose 35 percent to \$195.5 million, or \$0.70 per diluted share, compared with \$145.3 million, or \$0.52 per diluted share, in the first quarter of 2008. Non-GAAP net income grew 10 percent to \$288.1 million, or \$1.04 per diluted share, compared with \$260.9 million, or \$0.95 per diluted share, in the same period last year.

Genzyme generated approximately \$350 million in cash predominantly from operations during the first quarter. The company used \$162 million for continued investments in manufacturing



infrastructure, \$107 million to repurchase 2 million shares as part of a stock buyback program, and \$23 million to acquire intellectual property and common stock from Exact Sciences Corp.

Based on the expected growth rates of the company's businesses and the anticipated impact of several key growth drivers, Genzyme reaffirmed its revenue and earnings guidance for 2009. The company expects 2009 revenue of \$5.15 – \$5.35 billion and non-GAAP earnings per share of \$4.58.

“We came through the first quarter well despite the weak economy and unfavorable exchange rates, and we are on track to meet our financial objectives this year,” said Henri A. Termeer, Genzyme's chairman and chief executive officer. “Our broad geographic and product diversification, as well as the clinical value of our products, position us to manage through this period and continue to grow. We will see further progress and results over the coming months from our R&D investment in late-stage programs.”

Genzyme expects a number of catalysts to help drive growth during 2009, including the impact of revenue from two oncology products the company is acquiring from Bayer HealthCare and additional revenue from Campath® (alemtuzumab) as a result of that agreement; the reacceleration of Myozyme® (alglucosidase alfa) sales in Europe; the U.S. approval of alglucosidase alfa; and the ongoing launches of Mozobil® (plerixafor injection), Synvisc-One™ (hylan G-F 20) and Renvela® (sevelamer carbonate).

#### First Quarter Results

Within the Genetic Disease segment, Myozyme revenue was \$67.4 million, compared with \$67.3 million in the same period last year. Revenue reflects the company's inability to sell the product for use by late-onset Pompe patients in the United States, and a global supply management program under which adults with Pompe disease temporarily missed doses in order to preserve constrained supply for infants and children.

In February, Genzyme received European Commission approval of Myozyme produced at the 4000 L scale, which is enabling patients to resume regular infusion schedules. With the new supply in place, Genzyme has also resumed promotion of the product in European countries. During the second half of this year, the company will begin preparations to add a third 4000 L bioreactor to its Belgium facility to support Myozyme's growth over the longer-term. It is anticipated this bioreactor would be approved for commercial production in mid-2011.

In the United States, Genzyme remains on-track to submit an sBLA for the 4000 L product this quarter based on its comparability to the approved 160 L product, and the company has a meeting scheduled with the FDA to discuss this filing before it is submitted.

Genzyme has completed all the measures required to respond to the FDA warning letter regarding the company's Allston manufacturing facility, aside from one additional filling study for Aldurazyme® (laronidase). Genzyme is now awaiting the FDA re-inspection of the plant.

Genzyme is also in regular communication with the agency regarding the complete response letter for Lumizyme™ (alglucosidase alfa). The company has received final comments from the agency regarding the Risk Evaluation and Mitigation Strategy for the product, the verification study, and the label. Once the FDA inspection of the Allston facility is completed and Genzyme's corrective actions are deemed adequate, the agency will formally review the company's submission addressing all the items in the complete response letter. Genzyme anticipates approval late in the second quarter or in the third quarter.

Also in the Genetic Disease segment, Fabrazyme® (agalsidase beta) revenue was \$122.2 million, up 5 percent from revenue of \$116.5 million during the first quarter of 2008.

Cerezyme® (imiglucerase for injection) revenue was \$296.0 million, compared with \$304.3 million in the same period a year ago, reflecting the impact of foreign exchange. Genzyme continues to see growth in the number of patients initiating therapy. Sales of Aldurazyme were \$36.8 million, compared with \$37.0 million in the first quarter of 2008.

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53. Defendants knew or recklessly disregarded that the April 22, 2009, press release was materially false and misleading because it failed to disclose that the “constrained supply” of Myozyme was attributable to undisclosed contamination problems that had occurred during the fall of 2008.

54. On May 6, 2009, Genzyme held an Analyst Day Meeting, and despite the weak growth in Myozyme sales in the first quarter of the year (resulting from the above-mentioned shortage), Genzyme reaffirmed its revenue guidance of \$5.15-\$5.35 billion for 2009.

55. On May 21, 2009, Genzyme reported that it had submitted its final documentation addressing the FDA's outstanding issues related to the Lumizyme application, and stated that it had completed the measures required to respond to the FDA's warning letter regarding the Allston facility.

56. On June 16, 2009, Genzyme issued a press release revealing that it had detected a virus that impairs cell growth in one of six bioreactors at the Allston facility. The press release, titled “Genzyme Temporarily Interrupts Production at Allston Plant,” was the first public

disclosure of the prior contamination incidents at the Company's Allston and Geel facilities, and stated the following:

Genzyme Corporation (NASDAQ: GENZ) today announced that it has detected a virus that impairs cell growth in one of six bioreactors at its Allston Landing manufacturing facility. The company has decided to temporarily interrupt bulk production at the plant to sanitize the facility. Genzyme is collaborating with regulatory agencies as it works to resume production. The company expects the plant to be fully operational by the end of July.

The virus strain, Vesivirus 2117, has not been shown to cause human infection. It is known to interfere with the growth of CHO cells used to produce biologic drugs and was likely introduced through a nutrient used in the manufacturing process. Genzyme has now confirmed that this virus was the cause of declines in cell productivity at its Allston and Geel facilities in two previous instances in 2008, which were subsequently fully addressed. The company was able to detect the virus in this case using a highly specific assay it developed after standard tests were unable to identify the cause of the previous productivity declines. Genzyme is adding steps to increase the robustness of its raw materials screening and viral removal processes.

Current inventories for Cerezyme® (imiglucerase for injection) and Fabrazyme® (agalsidase beta) are not sufficient to meet projected global demand. The timing and extent of the Cerezyme supply constraint is being clarified and will be communicated as soon as possible. The company expects Fabrazyme supply constraints to occur for a limited period beginning in September. The company will work with physicians, patients and regulators to minimize the impact of this constraint.

"The patients who need these therapies are our priority," said Henri A. Termeer, Genzyme's chairman and chief executive officer. "We are confident in the quality of the products produced in Allston and in our ability to resolve the issue affecting the plant. The impact will be temporary."

Genzyme identified the virus at the Allston plant over the weekend. On Monday morning, the company submitted information to the FDA and EMEA on its findings. The company held a conference call with the FDA on Monday afternoon. With regulatory input, Genzyme is finalizing its action plan and assessing the business impact of this situation. The company will provide updated financial guidance as soon as possible.

57. As a result of this news, the Company's shares fell almost \$3 from the previous day's close of \$55.62, to close at \$52.75 on June 16, 2009 – a drop of nearly 5.5% on extremely heavy volume of approximately 17 million shares traded.

58. On June 25, 2009, Genzyme provided an update on the decontamination process

and the extent of the projected shortages of Cerezyme and Fabrazyme. As of late June, Genzyme expected sales of both products to be interrupted for six to eight weeks (compared to the initial projection of only a one month disruption for Cerezyme). A senior biotech analyst at Deutsche Bank, Mark Schoenebaum, projected that the shutdown would lower Genzyme's revenue by approximately \$245 million, while he had previously estimated it would cost only \$100 million.

### **Disclosures at the End of the Class Period**

59. Then, on the morning of July 22, 2009, Genzyme issued a press release announcing that, due to the shutdown of its Allston facility, it was lowering its 2009 earnings forecast from \$3.52 per share to a range of \$2.35 to \$2.90 per share. The press release stated the following, in pertinent part:

Genzyme Corp. (NASDAQ: GENZ) today reported that second-quarter revenue rose to \$1.23 billion, compared with \$1.17 billion in the same period a year ago, an increase of 5 percent. Including the \$66 million impact of unfavorable currency exchange rates, revenue grew 11 percent in the second quarter. Results reflect \$13 million in lost revenue due to the interruption of Cerezyme® (imiglucerase for injection) shipments associated with the temporary shutdown of the company's Allston manufacturing facility last month.

Second-quarter growth was driven by the reacceleration of Myozyme® (alglucosidase alfa) sales in Europe; strong U.S. launches of Synvisc-One™ (hylan G-F 20) and Mozobil® (plerixafor injection); new revenue from oncology products acquired from Bayer Healthcare; increased sales of Fabrazyme® (agalsidase beta); and double-digit growth in the company's genetic testing business.

GAAP net income rose to \$192.2 million, or \$0.70 per diluted share, compared with \$69.6 million, or \$0.25 per diluted share, in the second quarter of 2008. GAAP and non-GAAP net income in this year's second quarter reflect the \$15.7 million cost of remediation associated with the temporary shutdown of the Allston plant and the \$6.6 million impact of the fair value step-up of inventory acquired from Bayer Healthcare. GAAP net income in last year's second quarter reflects a \$175 million licensing fee associated with mipomersen.

Non-GAAP net income grew to \$232.5 million, or \$0.85 per diluted share, compared with \$107.0 million, or \$0.38 per diluted share, in the same period last year. Non-GAAP net income excludes stock compensation and certain items associated with the purchase accounting for the Bayer business acquisition.

Genzyme generated approximately \$281 million in cash during the second quarter, predominantly from operations. The company used approximately \$157 million primarily for investments in manufacturing.

“Results for the second quarter showed the strength of our diversified business, with many newer products, such as Synvisc-One, contributing to our growth,” said Henri A. Termeer, Genzyme’s chairman and chief executive officer. “We are working through the Allston manufacturing interruption in a constructive way. At the same time, we are continuing to build the company for the future, making progress in our late-stage pipeline and bringing new products to patients.”

#### Allston Progress and Updated 2009 Guidance

Genzyme last month announced that it had detected a virus that impairs cell growth in a bioreactor used for Cerezyme production at its Allston facility. The company decided to temporarily interrupt production at the plant – which was manufacturing Cerezyme, Fabrazyme and Myozyme – to sanitize the facility.

Genzyme has now completed the sanitization and is on-track to resume production at Allston this month. When manufacturing resumes, Allston will be fully dedicated to the production of Cerezyme and Fabrazyme. All Myozyme/Lumizyme™ (alglucosidase alfa) production will occur at the company’s 4000 L scale facility in Belgium. Genzyme has already taken the initial steps in the cell culture process necessary for the re-start of production of Cerezyme and Fabrazyme at Allston. The first release of both products is expected before the end of this year.

Cerezyme and Fabrazyme inventories are not sufficient to avoid shortages during the period of suspended production and recovery. Genzyme is working closely with treating physicians, other health care providers, patient communities and regulatory officials worldwide to support patients with Gaucher and Fabry disease during the temporary period of supply constraint. Treatment guidelines developed by expert physicians, patient group leaders and regulators are being implemented globally to help support doctors and patients in their decisions about product usage during this period, with the goal of conserving supply for the most vulnerable patients.

Genzyme is adjusting its 2009 financial guidance based on the estimated impact of the temporary Allston shutdown and revised assumptions about the timing of the expected availability of Lumizyme in the United States.

Cerezyme revenue guidance is being adjusted to \$750 million – \$1 billion from \$1.250 billion – \$1.275 billion. The lower end of the guidance range reflects a scenario in which Genzyme would not be able to release any of the remaining work-in-process Cerezyme material that was unfinished when the plant was shut down; the higher end reflects a scenario in which the company is able to finish and release a significant portion of this material. Genzyme has decided to discard the material from the end of the affected production run. The company is conducting additional testing of the remaining material and continuing its discussions with regulatory authorities to determine whether the material may be finished and released, and if so, what portion of the material.

Fabrazyme revenue guidance is being adjusted to \$510 million – \$520 million from \$560 million – \$570 million to reflect product supply constraints due to the temporary halt in production at Allston.

Myozyme revenue guidance is being adjusted to \$330 million – \$340 million from \$370 million – \$380 million. To provide more capacity in its Allston plant for Cerezyme and Fabrazyme, Genzyme has transitioned all Myozyme/Lumizyme production to its 4000 L Belgium facility, and is no longer manufacturing the product at the 2000 L scale. FDA approval of the 4000 L process, which is now anticipated in the first quarter of 2010, will be necessary to expand supply and support an increase in U.S. sales. Genzyme will begin to transition U.S. patients in the Myozyme Temporary Access Program from the product produced at the 2000 L scale to that produced at the 4000 L scale and will be providing 4000 L data to the FDA to support this transition. The PDUFA date for Lumizyme (the 2000 L product) is November 14. Upon approval, Genzyme will submit a supplemental BLA for the 4000 L process. Genzyme anticipates a four-month FDA review of the sBLA, and if the FDA acts by the PDUFA date, a potential approval by the end of March 2010.

Genzyme's gross margin guidance is being adjusted to a range of 72 – 73 percent of revenue from 75 percent.

Total 2009 revenue guidance is being adjusted to \$4.6 billion – \$5 billion from \$5.15 billion – \$5.35 billion.

GAAP EPS guidance is being adjusted to a range of \$1.74 – \$2.29 per diluted share from \$3.02 per diluted share and non-GAAP EPS guidance is being adjusted to a range of \$2.35 – \$2.90 per diluted share from \$3.52 per diluted share. Non-GAAP EPS excludes the impact of stock compensation expenses and acquisition-related items.

## Second-Quarter Results

Within the Genetic Disease segment, Myozyme revenue grew to \$79.3 million, compared with \$67.4 million in the first quarter of this year. This reflects the re-acceleration of European sales following the February E.U. approval of production at the 4000 L scale, which expanded supply. Second-quarter sales of Myozyme were \$77.2 million.

Genzyme has begun preparations to add a third 4000 L bioreactor to its Belgium facility to support the product's growth over the longer term. The company anticipates this bioreactor will be approved for commercial production in mid-2011.

Cerezyme revenue was \$298.1 million, compared with \$319.4 million in the same period last year. Revenue reflects both the impact of the temporary Allston shutdown as well as unfavorable currency exchange rates.

Genzyme is preparing to begin enrollment in two global, multi-center, phase 3 trials of Genz-112638, a potential new oral therapy for Gaucher disease type 1. The first, a randomized, double-blind, placebo-controlled study, will include untreated Gaucher disease patients. It is expected to

enroll 36 patients who will be treated for 9 months. The second trial will be a randomized conversion study involving patients who have previously received Cerezyme, with an anticipated enrollment of approximately 96 patients and a 9-month treatment period. Genzyme is seeking to accelerate the regulatory process for this product globally in order to speed its approval.

Sales of Fabrazyme grew 6 percent, rising to \$134.3 million from \$126.6 million during the same period last year. Including the \$8.2 million impact of unfavorable currency exchange rates, revenue grew 13 percent. Sales of Aldurazyme® (laronidase) were \$39.2 million, compared with \$38.8 million in the second quarter of 2008.

Construction continues on an additional manufacturing facility for Cerezyme and Fabrazyme in Framingham, Mass. The plant is expected to be mechanically complete by the end of this year, and FDA approval for commercial production is anticipated in mid-2011. This plant, which will include four 2000 L bioreactors, will provide substantial additional capacity to support the growth of the two products. Genzyme has already hired approximately 100 people associated with the start-up of this facility.

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60. In response to these announcements, one day after the end of the Class Period, the price of Genzyme shares dropped sharply, to close at \$51.21 on July 22, 2009, a decline of \$4.70 per share, or 8.4%, from the prior day's close.

### **LOSS CAUSATION**

61. Throughout the Class Period, Defendants' materially false and misleading statements and omissions concerning Genzyme's supply and manufacturing problems and projected earnings caused Genzyme's stock price to be inflated. As a result of Defendants' false and misleading statements and material omissions, Genzyme's common stock traded between \$70 per share and \$80 per share for most of the Class Period, reaching a Class Period high of \$83.25 on August 14, 2008.

62. Plaintiff and the other members of the Class suffered damages as a direct result of Defendants' fraudulent conduct described in this Complaint. But for Defendants' misrepresentations and omissions, Plaintiff and the members of the Class would not have purchased Genzyme's stock, or would not have purchased it at artificially inflated prices. When

the reality of Defendants' conduct and the true picture of Genzyme's manufacturing operations and revenue projections were revealed to the investing public, the price of Genzyme common stock declined significantly, as described above, causing damages to Plaintiff and other Class members.

### **ADDITIONAL ALLEGATIONS OF SCIENTER**

63. The Defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued by them were materially false and/or misleading; knew or recklessly disregarded the fact that such statements would be disseminated to the investing public; and knowingly and substantially participated in the issuance and dissemination of the public documents and statements. In addition, Defendants acted with scienter by intentionally failing to inform the market in a timely manner of material information. Defendants' intent to deceive and/or reckless disregard for the truth is demonstrated by direct evidence as well as circumstantial evidence supporting a strong inference of scienter.

64. Defendant Termeer was an active and culpable participant in the management of Genzyme, which involved ensuring that its manufacturing facilities were operating properly in order to sustain supply for its products and that any regulatory requirements impacting the manufacturing facilities had been met. Termeer was aware of the Company's contamination problems at the Geel and Allston facilities during the fall of 2008, and he either knew or should have known no later than June 26, 2008 about the GMP deviations that would later be set forth in the Form FDA 483 in October 2008. As the recipient of the Form 483, Termeer was unquestionably aware of the GMP deviations discussed therein by October 10, 2008. Termeer knew or recklessly disregarded that the supply of Myozyme was at risk and that violations of the FDA's GMPs would jeopardize the Company's ability to continue making its products and



obtain approval of Lumizyme. However, Termeer failed to disclose to investors in a timely fashion these problems, or their potential impact on Genzyme's financial results and operations.

**APPLICABILITY OF PRESUMPTION OF RELIANCE:  
THE FRAUD-ON-THE-MARKET DOCTRINE**

65. At all relevant times, the market for Genzyme's common stock was an efficient market for the following reasons, among others:

- a. Genzyme's stock met the requirements for listing, and was listed and actively traded on the Nasdaq stock exchange, a highly efficient and automated market;
- b. During the Class Period, the average weekly trading volume of Genzyme's stock was greater than two percent of the outstanding shares, justifying a strong presumption that the market for Genzyme's shares was efficient;
- c. As a regulated issuer, Genzyme filed periodic public reports with the SEC and the Nasdaq stock exchange;
- d. Genzyme regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- e. Genzyme was followed by over twenty securities analysts who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

66. The market for Genzyme's common stock promptly digested current information regarding Genzyme from all publicly available sources and reflected such information in

Genzyme's stock price. Under these circumstances, it is appropriate to presume that all purchasers of Genzyme common stock during the Class Period relied on the misstatements and omissions of Defendants herein.

**COUNT I**

**Violations of Section 10(b) of the Exchange Act**  
**And Rule 10b-5 Promulgated Thereunder**  
**Against All Defendants**

67. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein.

68. This Claim is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, on behalf of Plaintiff and all other members of the Class against all Defendants.

69. As alleged in this Complaint, throughout the Class Period, Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce, the mails and/or the facilities of a national securities exchange, made false and/or misleading statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Among other things, Genzyme's SEC filings and press releases contained materially false and/or misleading statements of fact and/or omitted material facts as described above.

70. Defendants' false and misleading statements and omissions were intended to and did, as alleged herein, (i) deceive the investing public, including Plaintiff and the other members of the Class; (ii) artificially inflate and maintain the market price of Genzyme's securities; and (iii) cause Plaintiff and the other members of the Class to purchase Genzyme's securities at

inflated prices.

71. Defendants were each individually and collectively responsible for making one or more of the statements and omissions alleged herein, by virtue of having prepared, reviewed, commented on, approved, signed, and/or disseminated documents which contained false and/or misleading statements of material fact and/or omitted facts necessary to make the statements therein not misleading.

72. Defendants made the false and/or misleading statements and omissions knowingly and intentionally, or in such an extremely reckless manner as to constitute willful deceit and fraud upon Plaintiff and other members of the Class who purchased Genzyme's common stock during the Class Period.

73. Defendants' false and/or misleading statements and omissions were made in connection with the purchase or sale of Genzyme's common stock.

74. In ignorance of the false and misleading nature of Defendants' statements and omissions, and relying directly or indirectly on those statements and/or upon the integrity of the market price for Genzyme's common stock, Plaintiff and the other members of the Class purchased Genzyme's common stock at artificially inflated prices during the Class Period. But for the fraud committed by the Defendants, Plaintiff and the members of the Class would not have purchased these securities at artificially inflated prices.

75. The market price for Genzyme's common stock declined materially upon the public disclosure of the facts that had previously been misrepresented or omitted by Defendants, as described above.

76. Plaintiff and the other members of the Class were substantially damaged as a direct and proximate result of their purchases of Genzyme's common stock at artificially inflated

prices and the subsequent decline in the price of those securities when the truth was revealed.

## **COUNT II**

### **Violations of Section 20(a) of the Exchange Act Against Defendant Termeer**

77. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein.

78. This Claim is brought on behalf of Plaintiff and all other members of the Class against defendant Termeer, pursuant to Section 20(a) of the Exchange Act.

79. Throughout the Class Period Termeer was a controlling person of Genzyme within the meaning of Section 20(a) of the Exchange Act. By virtue of his positions as President, Chief Executive Officer and Chairman of the Board of Directors of Genzyme, Termeer had the power to influence and control and did influence and control, directly or indirectly, the decision-making of Genzyme, including the content and dissemination of the various statements that Plaintiff contends are materially false and misleading. Termeer was provided with or had unlimited access to copies of Genzyme's press releases and public filings alleged by Plaintiff to be false and/or misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements, cause the statements to be corrected, or cause the statements to be made at an earlier time.

80. As set forth above, Genzyme violated Section 10(b) and Rule 10b-5 by its acts and omissions as alleged herein. As a direct and proximate result of Genzyme's wrongful conduct, Plaintiff and the Class suffered damages. As a controlling person of Genzyme, Termeer is liable pursuant to Section 20(a) of the Exchange Act for Genzyme's violations of Section 10(b) and Rule 10b-5.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment:

- A. Determining that this action is a proper class action pursuant to Rule 23 of the Federal Rules of Civil Procedure;
- B. Awarding compensatory damages against Defendants in favor of Plaintiff and all Class members for damages sustained as a result of Defendants' wrongdoing;
- C. Awarding Plaintiff and all Class members their costs and disbursements in this suit, including reasonable attorneys' fees and expert fees; and
- D. Awarding such other relief as the Court deems just and proper.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

Dated: August 3, 2009

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